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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,081	07/21/2003	Keith E. Dionne	19141-509	6001
30623	7590	10/20/2004	CIP2DIV12CON2	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,081

Applicant(s)

DIONNE ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim 1 is pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a biocompatible matrix formed of a hydrogen" which is indefinite since it is unclear how a matrix is formed from one hydrogen. Further clarification is requested.

Further, the recitation "substantially free of direct ionic bonding" is vague and indefinite. The numerical parameter of "substantially free" is unclear since the specification does not provide a definition. Further clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walthall et al (4,997,443) in view of Sefton (4,353,888).

Walthall et al teach an artificial tissue matrix containing a gel polymer and cells (abstract). The reference teaches the use of a polymer matrix to hold the cells in a unitary mass to

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promote cell reorganization, growth, and differentiation for normal functioning (col.3, lines 56-63). Walthall recognizes the teaches the criticality of selecting particle sizes such that the particle size should promote cell viability in a physiological environment wherein the diffusion of nutrients is possible and yet provide a satisfactory size wherein the particles are not attacked by humoral or cellular components of the host immune system. See column 4, lines 5-25.

Walthall does not teach an external diffusion jacket.

Sefton teaches implantable mammalian cells that are encapsulated in a polymeric membrane. The polymeric membrane allows passage of cell substrates and secretions, but prevents passage of larger molecules such as proteinaceous antibodies. Therefore, the viable cells secreting essential products can be transplanted into a host, and be protected against the immune reactions of the antibodies of the host, which would otherwise reject the foreign cells. The viable cells of the core are suspended in a non-solvent for the polymer. See column 2, lines 60-68.

Polymer with the desired characteristics such as non-toxicity in solution, biocompatible in solid form, i.e. free from contaminants, sterilizable, implantable without causing inflammatory or immune response, and either non-biodegradable or of controlled biodegradability. Examples of suitable polymers taught are polyacrylates and copolymers with acrylic acid, methacrylic acid and esters thereof, cellulose based polymers, copolymers containing acrylamides, N-vinyl pyrrolidone, styrene sulphonate, vinyl pyridine, vinyl alcohol, and the like. A copolymer of acrylic acid ester and methacrylic acid ester is preferred. See column 3, lines 13-35.

Sefton does not teach a matrix core.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Walthall et al and Sefton and utilize Sefton's polymeric

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membrane to further encapsulate the implantable cells. One would have been motivated to do so since Sefton teaches the use of the polymeric membrane not only provides the cells with sufficient nutrients and allows the passage of the cells' secretions, but it also protects the implant from the host's immune system by preventing the diffusion of the host's antibodies into the implant. Therefore, since Walthall recognizes the criticality of preventing cell immune response to the implant while simultaneously providing nutrients to the implant, one would be motivated to look to Sefton, who provides the solution to this problem using a semipermeable membrane.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1 of U.S. Patent No. 5,800,828, 6,083,523, 5,955,095, and 6,322,804. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant application and US patents are related as genus-species.

Instant claim recites an implantable device comprising (a) a core comprising living cells dispersed in a biocompatible matrix formed of a hydrogen, said cells being capable of secreting a

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selected biologically active product and (b) an external diffusional surface jacket surrounding said core formed of a biocompatible hydrogel material free of said cells projecting externally and having a molecular weight cutoff below the molecular weight of substances essential for immunological rejection of the cells.


US patent '828 claims (a) a core containing in excess of 1ul and at least about 10^4 living cells and (b) an external jacket greater than 5 microns thick with the instant recited properties.

US patent '523 claims (a) a core containing in an excess of 1ul and at least about 10^4 living cells and (b) an external jacket greater than 5 microns thick with the instant recited properties.

US patent '804 claims (a) a core containing at least about 10^4 living cells and (b) an external jacket having a thickness of 5 to 200 microns with the instant recited properties.

US patent '095 claims (a) a core containing living cells that are capable of secreting active products (b) an external jacket which is substantially free of cells and having a molecular weight cutoff greater than about 440kD.

Thus, the instant claim recites the broader scope, which encompasses the subject matter of the US patent cited above. Therefore, the instant application and the US patents cited above have a genus-species relationship wherein the instant claim anticipates the claims of US patent 5,800,828, 6,083,523, 5,955,095, and 6,322,804.


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